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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,594	11/07/2001	Atul D. Ayer	ARC 2483N2	8494

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EXAMINER	
OH, SIMON J	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,594	AYER ET AL.	
	Examiner	Art Unit	
	Simon J. Oh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 39-53 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 39-53 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Numbering of Claims

1. The applicant is notified of the re-numbering of the claims in the application, as per 37 CFR 1.126.

Priority

2. Receipt is acknowledged of the applicant's preliminary amendment and Information Disclosure Statement, received on November 7, 2001.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 39-53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,096,339. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the '339 patent are directed to a "controlled drug rate of release"; although such a rate of release is not explicitly defined within the claims of the '339 patent, one of ordinary skill in the art would recognize that a dosage form which delivers a drug at a rate which deviates not more than 5% from the mean release rate, as embodied in the claims of the instant application, would provide a substantially uniform, and thus a "controlled drug rate of release".

Additionally, verapamil hydrochloride is named as a specific drug to be used in the instantly claimed invention. Although the '339 patent lists verapamil among other drugs in Claims 11, 16, and 28, and does not specifically mention the use of pharmaceutically salts thereof, Claim 13 lists the use of different categories of drugs, among which are calcium channel blockers; verapamil hydrochloride falls into this category, and it would be obvious to one of ordinary skill in the art that the various categories of drugs listed in Claim 13 of the '339 patent would encompass pharmaceutically acceptable salts of the drugs listed in Claims 11, 16, and 28.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 39-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jao *et al.* (U. S. Pat. No. 5,151,338)

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The Jao *et al.* patent teaches a dosage form which provides for the delayed release of a drug, and a way to provide treatment with such a dosage form (See Column 2, Lines 39-55; Column 6, Lines 52-68; and Column 22, Lines 17-62). Within the dosage form, the drug is mixed with a polymer, which draws in fluid in order to change into a semi-fluid or viscous state for dispensing the drug, with polyethylene oxide being the preferred material (See Column 8, Line 66 to Column 9, Line 41). Various types of drugs can be used in the dosage unit, including calcium channel inhibitors (See Column 7, Line 68 to Column 8, Line 1). Verapamil is listed among specific drugs that can be used in the dosage form (See Column 8, Line12), and hydrochlorides are named among acceptable salts that can be used as an alternate form of drugs that may be used (See Column 8, Lines 48-49). Furthermore, the Jao *et al.* patent describes the manufacture of dosage forms, with verapamil hydrochloride as the drug, and the release profiles of these dosage forms (See Example 12, and Figures 14-18 of the Jao *et al.* patent and compare

with Example 6 of the instant application). The dosage forms described in Example 12 provide means for delaying the release of the drug for up to 3 hours, at which point, the drug is released in what appears to be substantially consistent rates of release for a period of time greater than 4 hours. The Jao *et al.* patent does not specifically mention the feature of a percentage deviation of not more than 5% from a mean rate of release, nor does it specifically mention the feature of controlled particle sizes of the drug or the hydrophilic polymer. Therefore, it is the opinion of the examiner that such features are not critical to the function of the claimed invention, and the invention as a whole is *prima facie* obvious

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Simon J. Oh
Patent Examiner
AU 1615

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